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**PATENT**

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November 14, 2005

Cynthia P. Scanio November 14, 2005  
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

*Ex parte* DING ET AL.

Appeal No. \_\_\_\_\_

Serial No.: 09/268,437  
Filed: March 12, 1999  
Group Art Unit: 1641  
Examiner: Gailene R. Gabel  
Applicant: Ying Ding, Brian Halsall and William R. Heineman  
Title: SIMULTANEOUS MILTIANALYTE ELECTROCHEMICAL  
ASSAY BASED ON SPATIAL RESOLUTION

Cincinnati, Ohio 45202

November 14, 2005

**Mail Stop Appeal Brief-Patents  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450**

**REPLY BRIEF**

This is in reply to the Examiner's Answer mailed November 2, 2005.

**The Henkens et al. Reference**

The disclosure in Henkens et al. US Patent 6,391,558 is not an appropriate reference. The Examiner has cited specific language from the Henkens reference as the

basis of the Section 102(e) rejection of claims 1-5, 11 and 12. She as specifically referenced column 6, lines 32-38 and FIG. 14, column 4, line 41 to column 6, line 38; column 19, line 58 to column 20, line 56; column 17, line 51 to column 18, line 63; and column 41, lines 31-38, yet she has failed to establish that the disclosure on which she is relying was present in the original filed provisional application. There is no presumption that a continuation-in-part has the same disclosure as its parent or related applications. If the Examiner wants to rely on the disclosure of the provisional, and can cite portions from the provisional, she should have done so.<sup>1</sup>

Accordingly, as it stands, there is no valid reference cited against claims 1-5 and 12.

#### The Henkens Reference Does Not Anticipate the Pending Claims

Applicants' invention uses a plurality of working electrodes with a single reference electrode. Each working electrode measures the same product. But, each working electrode is detecting a different substance. That is not the case with the devices disclosed in the Henkens reference. But, in particular, the Henkens reference fails to disclose a single reference electrode working with a plurality of working electrodes. The Examiner has stated that "Henkens et al teach that whether an array of working electrodes or a single working electrode, the electrochemical assay device may optionally include a common (1) reference or counter electrode or more reference or counter electrodes." There is no support for this statement in the Henkens reference. The device disclosed in Henkens will not function without having a single reference electrode associated with a

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<sup>1</sup>The Examiner has indicated that she has, in fact, sent a copy of the Henkens provisional application to applicant. But, as of the filing of this reply it has not been received.

single working electrode. In an attempt to respond to this argument, the Examiner refers to Column 6, lines 33-38, of the Henkens reference. That portion of the Henkens reference teaches a single reference electrode for a single working electrode. Nowhere does Henkens suggest that there can be a plurality of working electrodes and a single reference electrode.

The Examiner then goes on to make the statement, "Henkens et al proceeds to teach that "whether in an array or a single electrode, the biosensor may optionally include one, i.e., common or more (counter) electrodes", as cited in the rejected claims." What the reference actually states is **"Whether in an array or a single working electrode, the biosensor may optionally include one or more counter electrodes."** The Examiner has mis-quoted the Henkens reference.

Who knows what is specifically taught in the Henkens provisional application as filed? Not to belabor the point, but the Examiner's inaccurate quote from the Henkens reference points out applicants frustration in having this cited as a reference as opposed to the disclosure in the provisional application.

But, without a doubt, the Henkens reference fails to disclose a reference electrode associated with a plurality of working electrodes as required by applicants' claims.

With respect to claim 11, the Henkens reference does not disclose that all of the binding areas are coated with a single quiescent solution containing substrate reactive with enzymes bonded to analyte binding areas as claimed in claim 11. Again, applicants' invention utilizes electrodes all measuring the same product, whereas the Henkens reference relies on each of the electrodes measuring a different product.

Therefore, they would not coat all of the binding areas with a single solution containing substrate reactive with enzymes bonded to analyte binding areas.

The Cozzette et al. Reference Does Not Anticipate Claim 11

The Examiner has withdrawn her rejection under 35 U.S.C. §102 of claim 12 based on the Cozzette et al. reference. This leaves the rejection of claim 11 based on the Cozzette reference. As previously indicated, applicants' have claimed the structure wherein the binding areas are coated with a single quiescent solution. In other words, the assay structure is being claimed during use. The Cozzette reference teaches a method of fabricating sensors onto, for example, a silicon chip. The individual sensors are then cut into individual sensors to be then used. There is no disclosure of a device having more than one sensor, each with an analyte binding area. The Cozzette reference actually discloses a wide variety of different sensors including glucose sensors, ligand/ligand receptor based biosensors, blood urea nitrogen sensors, automated microdispensing systems, and other specific sensors.

Again, this reference does not teach the features as stated by the Examiner. The disclosure at column 22, lines 17-35 simply discloses that different sensors use different enzymes. Generally, the sensors are intended to be separated. Certainly, all of the disclosed sensors which use analyte binding areas are intended to be separated.

The structure disclosed in FIG. 4 is not the same type of sensor as applicant is claiming. Nor is it the same as the sensor referenced at column 22. The sensor shown in FIG. 4 does not utilize a plurality of analyte binding areas. FIG. 3 shows the particular sensor. It does not have an analyte binding area. There are no analyte binding substrates

on the structure shown in FIGS. 3 or 4 in the Cozzette reference. There is a film forming layer which incorporates an enzyme that reacts with urea to form ammonia. But, there is no analyte binding area. Further, this device would never be covered with a single quiescent solution containing substrate reactive with enzymes bonded to the analyte binding area.


Further, the device shown in FIG. 4 states "In particular embodiments of the instant invention, other indicator electrodes may be present in the biosensor for the simultaneous measurement of ionic species (e.g.,  $\text{Na}^+$ ,  $\text{K}^+$  or  $\text{Cl}^-$ ) in addition to ammonium ion. Cozzette fails to disclose the structure of these indicator electrodes. Thus, there is no way to say whether these have any type of analyte binding area. This is the only disclosure in the Cozzette reference cited by the Examiner wherein different sensors are designed to operate simultaneously. Thus, the Cozzette reference fails to disclose applicants' invention as claimed in claim 11.

In light of the above, applicants' would request allowance of the pending claims.

Respectfully submitted,

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